

DETAILED ACTION

Claims 1-57 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-20, 37-48, 50-57, drawn to a thrombin derivative comprising an A chain and a B chain, wherein the B chain has an amino acid sequence in which one or more kinds of active center amino acids selected from the group consisting of S205, G203, D99, H43 in the B chain are substituted.

Group II, claim(s) 21, 25-26, 34-35, drawn to a thrombin derivative wherein the B chain has an amino acid sequence in which amino acids except the active center amino acids are further substituted and has a VIIIA/FA ratio of 1.1 folds or more.

Group III, claim(s) 21, 27-30, 34-35, drawn to a thrombin derivative wherein the B chain has an amino acid sequence in which amino acids except the active center amino acids are further substituted and has a VIIIA/TMA ratio of 1.1 folds or more.

Group IV, claim(s) 22-24, drawn to a thrombin derivative wherein the B chain has an amino acid sequence in which amino acids in an exosite I region of thrombin are substituted.

Group V, claim(s) 31-33, 36, drawn to a thrombin derivative where the B chain has an amino acid sequence in which amino acids in an exosite II region of thrombin are substituted.

Group VI, claim(s) 49, drawn to a DNA encoding a thrombin derivative comprising an A chain and a B chain, wherein the B chain has an amino acid sequence in which one or more kinds of active center amino acids selected from the group consisting of S205, G203, D99, H43 in the B chain are substituted.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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The technical feature linking groups I-VI appears to be that they all relate to a thrombin derivative with a substitution in the B chain amino acid.

However, Arcone et al. (1999 *Biochimica et Biophysica Acta* 1451: 173-186; IDS 06.28.07) teach a thrombin derivative with B chain amino acid substitutions.

Therefore, the technical feature linking the inventions of Groups I-VI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

blood coagulation factor 13, fibrinogen (claims 4-5);

APTT-prolonging effect, a thrombin receptor activation-inhibiting effect, ristocetin-induced platelet aggregation-inhibiting effect (claims 27-28);

activated partial thromboplastin time-prolonging effect, a modified thrombin-induced platelet aggregation-inhibiting effect, ristocetin-induced platelet aggregation-inhibiting effect (claim 34);

ester of an amino acid, polyethylene glycol, carbodiimide (claims 40-41, 44)

antithrombotic agent, anti-inflammatory agent, platelet aggregation-inhibiting agent, platelet adhesion-inhibiting agent, endogenous blood coagulation-inhibiting agent, thrombin receptor activation-inhibiting agent, anti-blood coagulation effect/antiplatelet effect (claims 51-57)

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-2, 27-28, 34, 39, 50.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the above named species are chemically and structurally different compounds and/or different activities of thrombin, which will all have different properties.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/
Primary Examiner, Art Unit 1656

December 30, 2009

M. Tsay
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